K010049

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LiDCO Cardiac Sensor Systems

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510(k) Summary of Safety and Effectiveness

SUBMITTED BY:

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CONTACT:

Gregory Speller
Quality & Regulatory Manager

DATE PREPARED:

31st December 2000

PRODUCT (TRADE) NAME:

PulseCO Hemodynamic Monitor (Model No. CM 71)

COMMON NAME:

Cardiac Output and Hemodynamic Parameters Computer

CLASSIFICATION NAME:

Programmable Diagnostic Computer (21 CFR 870.1425)

REASON FOR SUBMISSION:

LiDCO Ltd. has developed, and intends to market, the PulseCO Hemodynamic Monitor. The monitor improves the sensitivity and specificity of invasive arterial pressure monitoring currently used in the I.C.U., Operating Room, H.D.U., etc. by functioning as an "early warning system" of change from a pre-determined hemodynamic state.

PREDICATE DEVICE IDENTIFICATION:

The PulseCO Hemodynamic Monitor is substantially equivalent to the Vigilance Continuous Cardiac Output / Oximetry Monitor marketed by Baxter Healthcare Corporation, and cleared for marketing under Premarket Notification K955816.

SPECIAL CONTROLS (SECTION 514):

There are no requirements or special controls under Section 514 of the FD & C Act that are applicable to the PulseCO Hemodynamic Monitor or to the predicate device.

GENERAL DESCRIPTION:

The PulseCO Hemodynamic Monitor consists of a proprietary panel p.c. fitted with an analog-to-digital converter card, and loaded with the Operating System software and the PulseCO algorithm software.

The monitor complies with the electrical safety requirements of IEC601-1 and with the EMC requirements of IEC601-1-2.

The PulseCO Hemodynamic Monitor is connected to the output connector of a blood pressure monitor that is attached to the patient. The analog signal from the B.P. monitor is digitized, and the signal is then analyzed and the measured heart rate and blood pressure is displayed.

Keying in, via the touch screen, the cardiac output of the patient (which has been obtained during a standard indicator dilution measurement) allows the software to derive an indication of change of blood flow, which is displayed on the monitor screen.

The displayed hemodynamic parameters are: Heart Rate, Blood Pressure, Systemic Vascular Resistance, Cardiac Output and Stroke Volume

No diagnostic decisions are made by the software. The software is not intended to replace the need for a skilled clinician or nurse, but is intended to aid the clinician or nurse in identifying changes in blood flow.

INTENDED USE:

The PulseCO Hemodynamic Monitor is intended for deriving and monitoring hemodynamic and cardiac parameters in patients with pre-existing peripheral arterial line access.in Medical and Surgical Intensive Care Units, Operating Rooms, Step Down/High Dependency Units, Trauma and Accident & Emergency Units, Coronary/Intensive Care Units and Catheter Labs.

COMPARATIVE INFORMATION (SIMILARITIES AND DIFFERENCES):

Labelling:
The table comparing the PulseCO Hemodynamic Monitor with the Baxter Vigilance Continuous Cardiac Output Monitor was compiled from the pre-market notification and available product literature for the devices. The comparison illustrates that the devices are similar in intended use, physical characteristics, target population, and safety characteristics.

Intended Use:
The PulseCO Hemodynamic Monitor and the Baxter Vigilance Continuous Cardiac Output Monitor are intended for patients for whom the monitoring of continuous cardiac output and derived hemodynamic parameters are indicated for diagnostic and prognostic evaluation by a clinician.

Physical Characteristics:
The PulseCO Hemodynamic Monitor and the Baxter Vigilance Continuous Cardiac Output Monitor are both microprocessor based electronic devices.

Anatomical Sites:
The Baxter Vigilance Continuous Cardiac Output Monitor is connected to a thermodilution catheter which is placed in the pulmonary artery. The PulseCO Hemodynamic Monitor has no patient-applied parts. It is connected to the analog output of a blood pressure monitor already attached to the patient (via a transducer in the arterial line).

Target Population:
The target population for both products includes patients for whom hemodynamic monitoring will improve their clinical care.

Performance Testing:

Bench Testing:
Patients' B.P. traces, previously recorded in a variety of clinical environments, were input into the PulseCO Hemodynamic Monitor and the outputs compared to the original values. These evaluations demonstrate that the PulseCO Hemodynamic Monitor meets the specifications and is substantially equivalent to the predicate device.

Animal Testing:
Due to the fundamental differences between the hemodynamics of animals and humans, animal testing of the PulseCO Hemodynamic Monitor was not considered appropriate. The comprehensive bench testing was more suitable and gave more meaningful results.

Clinical Testing:
The PulseCO Hemodynamic Monitor has been evaluated in a number of clinical situations. These evaluations demonstrate that the PulseCO Hemodynamic Monitor meets the specifications and is substantially equivalent to the predicate device

Safety Characteristics

A Hazard Analysis was conducted to identify any hazards relating to the components or use of the PulseCO Hemodynamic Monitor, and to evaluate the risks associated with those hazards. All hazards were reviewed, and, where necessary, testing was carried out to ensure that effective corrective action had been implemented.

The Electrical Safety Certification and the results of the accuracy testing show that the PulseCO Hemodynamic Monitor is comparable to the predicate device with regards to safety.

SOFTWARE VERIFICATION & VALIDATION:

Hazard Analysis:

Any potential hazards associated with the software were identified during the Hazard Analysis, and corrective actions were implemented to eliminate each hazard or to minimize the risk of the hazard arising.

Level of Concern:

Based upon the intended use and the potential hazards of the device, the PulseCO Hemodynamic Monitor has been determined to have a minor level of concern. This differs from the predicate device (moderate level of concern) due to the absence of any patient applied part.

Development Documentation:

Software is developed at LiDCO Ltd. in accordance with IEC601-1-4 "General requirements for programmable electrical medical systems" and in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

All software components were tested and documented appropriately, in accordance with LiDCO Ltd.'s ISO9001 certified Quality System & Procedures.

SUMMARY:

The PulseCO Hemodynamic Monitor is substantially equivalent to the predicate device. the Baxter Vigilance Continuous Cardiac Output Monitor.

Gregory Speller - Quality & Regulatory Manager
On behalf of LiDCO Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2001

LiDCO Ltd.
c/o Mr. Charles Kyper
Kyper & Associates
103 Nolen Lane
Chapel Hill, NC 27516

Re: K010049
Trade Name: PulseCO Hemodynamic Monitor, Model CM-71
Regulation Number: 870.1435
Regulatory Class: II (two)
Product Code: DXG
Dated: April 24, 2001
Received: April 26, 2001

Dear Mr. Kyper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Applicant: **LiDCO Ltd., London, U.K.**

510(k) Number (if known): K010049

Device Name: **PulseCO Hemodynamic Monitor**

INDICATIONS FOR USE:

The PulseCO Hemodynamic Monitor is intended for monitoring continuous blood pressure and cardiac output in patients with pre-existing peripheral arterial line access.

In addition to arterial blood pressure parameters and cardiac output, the PulseCO Hemodynamic Monitor calculates a number of derived parameters: Body Surface Area, Systolic Pressure Variation, Cardiac Index, Stroke Volume, Stroke Volume Index, Systemic Vascular Resistance, Systemic Vascular Resistance Index.

SUITABLE PATIENTS:

Patients who have peripheral arterial access and require cardiovascular monitoring.

LOCATIONS OF USE:

Suitable patients will be receiving treatment in the following areas:

Medical and Surgical Intensive Care Units
Operative Suites
Step Down / High Dependency Units
Trauma / Accident & Emergency Departments
Coronary Intensive Care Units
Cath. Laboratory

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010049

Prescription Use____
(Per 21CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)